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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,891	12/22/2003	Jonathan P. Duvick	P05573US04-PHI 1134RD	2479

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/743,891

Applicant(s)

DUVICK ET AL.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, Claims 1-10, in the reply filed on 08/30/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is made FINAL.

Claims 1-11 are pending.

Claim 11 is withdrawn from consideration as being directed to the non-elected invention.

Claims 1-10 are examined in this application.

Priority

The status of the parent applications 09/658,835; 09/352,159; and 09/352,168 listed in page 1 of the specification, should be updated.

Specification

The disclosure is objected to because of the following informalities: for example, page 79, line 8, contains an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser- executable code are not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser- executable code. See MPEP 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated APAO polynucleotide encoding SEQ ID NO: 51, host cells and plant/seed transformed with said polynucleotide, does not reasonably provide enablement for an isolated polynucleotide from any source having at least 90% identity to SEQ ID NO: 50 and encoding a functional polypeptide having APAO activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to an isolated APAO polynucleotide having at least 90% sequence identity to SEQ ID NO: 50, a recombinant DNA construct comprising said polynucleotide, a vector comprising said DNA construct, host cells and plant/seed transformed with said polynucleotide. In contrast, the specification teaches that SEQ ID NO: 50 encoding a polypeptide with APAO activity. Applicant has not provided guidance for any modifications to SEQ ID NO: 50 which resulted a polynucleotide having at least 90% sequence identity thereto and still encoding a polypeptide having APAO activity. Applicant has not taught which region in the SEQ ID NO: 50 is necessary to encode a functional polypeptide having APAO activity. While fumonisin degrading enzymes can be obtained from a variety of sources, not all isolates are able to degrade

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fumonisin. For example, US PAT. 6, 025, 188, teaches that several other *Exophiala* species (other than *E. Exophiala*) and non-maize *Rhinocladiella* isolates didn't degrade fumonisin or fumonisin related compounds (column 7, lines 4-9). Applicant has provided no guidance regarding the working conditions necessary to obtain polynucleotide from non-maize *Rhinocladiella* and non- *E. Exophiala* sources capable of encoding a polypeptide having fumonisin degrading activity.

Therefore, given the breadth of the claims; lack of guidance; unpredictability; the state of the art as discussed above; and lack of working examples, undue trial and error experimentations would have been required by one skilled in the art to practice the invention as broadly claimed.

See Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are drawn to isolated polynucleotides having at least 90% identity to SEQ ID NO: 50 and encoding a polypeptide having APAO activity. The specification

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describes polynucleotides from *Exophiala spinifera*, *Rhinocladia atrovirens* or the bacteria of ATCC Accession No. 55552 isolates from maize seed. The scope of the claims encompasses genus of nucleic acids from all natural sources having 90% sequence identity. Applicant has not described specific structural characteristics common to all fumonisin degrading APAO encoding sequences, and a review of literature does not indicate that such characteristics would be well known by a skilled artisan. Therefore, the disclosure of few polynucleotides from *Exophiala spinifera*, *Rhinocladia atrovirens* would not provide adequate written description for all the polynucleotides as broadly claimed.

The *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997) states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. In this Application, Applicant has neither disclosed a representative number of polynucleotides nor provided a structural feature common to all members of the genus. Therefore, the written description requirement is not satisfied. Because Applicant has not described the polynucleotides as broadly claimed, plants and plant cells

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comprising them are similarly not described. Therefore, weighing all factors above, a person skilled in the art would not recognize from the disclosure that Applicant was in possession of the invention. See, Written Description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices):

Remarks

Claims 1-10 are free of the prior art of record.

No claim is allowed.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

9/13/06

Mai

MEDINA A. IBRAHIM
PRIMARY EXAMINER

Medina A. Ibrahim